ASTRA-OCT SPINE SYSTEM

ASTRA-OCT Spine System
Posterior Cervical
Surgical Techniques

SpineCraft

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ASTRA OCT SPINE SYSTEM

DEFORMITY SURGICAL TECHNIQUES

Disclaimer

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01. Introduction

Dear Colleagues,

The ASTRA-OCT Spine System, when used as a top-loading, top-tightening system, answers spine surgeons' pursuit for optimal occipito-cervico-thoracic deformity correction.

Cervical deformity correction requires a comprehensive selection of implants and well-designed instruments; the ASTRA-OCT Spine System was designed to provide both.

The ASTRA-OCT Spine System allows for different techniques of rod reduction, with a wide selection of rod manipulation instruments, various lateral mass and pedicle screws, reduction screws, hooks, and cross connectors.

The ASTRA-OCT Spine System is a comprehensive universal system that offers significant performance and ease of use benefits and brings innovation, versatility, and reliability to various spine surgery procedures.

Sincerely,

Steven Mardjetko, MD

02. Description

The ASTRA-OCT Spine System is a screw/hook and rod system for stabilization of the cervical and thoracic spine. It utilizes Ø3.5mm & Ø4.0mm titanium alloy or cobalt chrome alloy rods, polyaxial single-lead thread screws with standard or smooth shanks, standard or reduction tulips, cross connectors, lateral connectors, rod-to-rod connectors, and hooks.

ASTRA-OCT Spine System Key Features:

- The system employs 3.5mm or 4.0mm rod diameter made of titanium alloy or cobalt chrome alloy.
- All standard polyaxial screws and hooks are very compact, yet strong, for optimum performance with different rod material choices.
- All screws are designed with Dual Core Technology.
- All ASTRA-OCT screws have a single-lead thread design with optimized cortical and cancellous zones.
- Polyaxial screws screws are available in 3.5, 4.0, 4.5, 5.0, and 5.5mm diameters and start from 10mm length. Reduction screws are also available in different diameters and lengths. This makes the system particularly suitable for deformity correction.
- All polyaxial screws are available as self-tapping.
- ASTRA-OCT polyaxial screws have a friction-fit head designed to facilitate rod placement in deformity and complex spine procedures.
- The ASTRA-OCT Spine System includes a cross connector design, which provides very low profile and versatile connection between the two rods, regardless of their orientation or level.
- ASTRA-OCT titanium hooks & screws are color-coded by screw diameter/hook throat size.

Polyaxial Screws	Catalog n°
Ti Poly Screw Ø3.50 x 10mm	A3P-3510
Ti Poly Screw Ø3.50 x 12mm	A3P-3512
Ti Poly Screw Ø3.50 x 14mm	A3P-3514
Ti Poly Screw Ø3.50 x 16mm	A3P-3516
Ti Poly Screw Ø3.50 x 18mm	A3P-3518
Ti Poly Screw Ø3.50 x 20mm	A3P-3520
Ti Poly Screw Ø3.50 x 22mm	A3P-3522
Ti Poly Screw Ø3.50 x 24mm	A3P-3524
Ti Poly Screw Ø3.50 x 26mm	A3P-3526
Ti Poly Screw Ø3.50 x 28mm	A3P-3528
Ti Poly Screw Ø3.50 x 30mm	A3P-3530
Ti Poly Screw Ø3.50 x 32mm	A3P-3532
Ti Poly Screw Ø3.50 x 34mm	A3P-3534
Ti Poly Screw Ø4.00 x 10mm	A3P-4010
Ti Poly Screw Ø4.00 x 12mm	A3P-4012
Ti Poly Screw Ø4.00 x 14mm	A3P-4014
Ti Poly Screw Ø4.00 x 16mm	A3P-4016
Ti Poly Screw Ø4.00 x 18mm	A3P-4018
Ti Poly Screw Ø4.00 x 20mm	A3P-4020
Ti Poly Screw Ø4.00 x 22mm	A3P-4022
Ti Poly Screw Ø4.00 x 24mm	A3P-4024
Ti Poly Screw Ø4.00 x 26mm	A3P-4026
Ti Poly Screw Ø4.00 x 28mm	A3P-4028
Ti Poly Screw Ø4.00 x 30mm	A3P-4030
Ti Poly Screw Ø4.00 x 32mm	A3P-4032
Ti Poly Screw Ø4.00 x 34mm	A3P-4034
Ti Poly Screw Ø4.50 x 20mm	A3P-4520
Ti Poly Screw Ø4.50 x 24mm	A3P-4524
Ti Poly Screw Ø4.50 x 28mm	A3P-4528
Ti Poly Screw Ø4.50 x 30mm	A3P-4530
Ti Poly Screw Ø4.50 x 32mm	A3P-4532
Ti Poly Screw Ø4.50 x 36mm	A3P-4536
Ti Poly Screw Ø4.50 x 40mm	A3P-4540
Ti Poly Screw Ø4.50 x 44mm	A3P-4544
Ti Poly Screw Ø5.00 x 20mm	A3P-5020
Ti Poly Screw Ø5.00 x 25mm	A3P-5025
Ti Poly Screw Ø5.00 x 30mm	A3P-5030
Ti Poly Screw Ø5.00 x 35mm	A3P-5035
Ti Poly Screw Ø5.00 x 40mm	A3P-5040
Ti Poly Screw Ø5.00 x 45mm	A3P-5045
Ti Poly Screw Ø5.50 x 30mm	A3P-5530
Ti Poly Screw Ø5.50 x 35mm	A3P-5535
Ti Poly Screw Ø5.50 x 40mm	A3P-5540
Ti Poly Screw Ø5.50 x 45mm	A3P-5545

Available on all screws:
Standard angulation is ± 40°
Favored Angle is up to 45° Cephalad-Caudal
Favored Angle is up to 55° Medial-Lateral

Additional screw sizes available upon request.

Reduction Screws

Polyaxial Reduction Screws	Catalog n°
Ti Poly Reduction Screw Ø3.50 x 10mm	A3P-3510R
Ti Poly Reduction Screw Ø3.50 x 12mm	A3P-3512R
Ti Poly Reduction Screw Ø3.50 x 14mm	A3P-3514R
Ti Poly Reduction Screw Ø3.50 x 16mm	A3P-3516R
Ti Poly Reduction Screw Ø3.50 x 18mm	A3P-3518R
Ti Poly Reduction Screw Ø3.50 x 20mm	A3P-3520R
Ti Poly Reduction Screw Ø3.50 x 22mm	A3P-3522R
Ti Poly Reduction Screw Ø3.50 x 24mm	A3P-3524R
Ti Poly Reduction Screw Ø3.50 x 26mm	A3P-3526R
Ti Poly Reduction Screw Ø3.50 x 28mm	A3P-3528R
Ti Poly Reduction Screw Ø3.50 x 30mm	A3P-3530R
Ti Poly Reduction Screw Ø3.50 x 32mm	A3P-3532R
Ti Poly Reduction Screw Ø3.50 x 34mm	A3P-3534R
Ti Poly Reduction Screw Ø4.00 x 10mm	A3P-4010R
Ti Poly Reduction Screw Ø4.00 x 12mm	A3P-4012R
Ti Poly Reduction Screw Ø4.00 x 14mm	A3P-4014R
Ti Poly Reduction Screw Ø4.00 x 16mm	A3P-4016R
Ti Poly Reduction Screw Ø4.50 x 20mm	A3P-4516R
Ti Poly Reduction Screw Ø4.50 x 20mm	A3P-4520R
Ti Poly Reduction Screw Ø4.50 x 24mm	A3P-4524R
Ti Poly Reduction Screw Ø4.50 x 28mm	A3P-4528R
Ti Poly Reduction Screw Ø4.50 x 32mm	A3P-4532R
Ti Poly Reduction Screw Ø4.50 x 36mm	A3P-4536R
Ti Poly Reduction Screw Ø4.50 x 40mm	A3P-4540R
Ti Poly Reduction Screw Ø4.50 x 44mm	A3P-4544R
Ti Poly Reduction Screw Ø5.00 x 20mm	A3P-5020R
Ti Poly Reduction Screw Ø5.00 x 25mm	A3P-5025R
Ti Poly Reduction Screw Ø5.00 x 30mm	A3P-5030R
Ti Poly Reduction Screw Ø5.00 x 35mm	A3P-5035R
Ti Poly Reduction Screw Ø5.00 x 40mm	A3P-5040R
Ti Poly Reduction Screw Ø5.00 x 45mm	A3P-5045R
Ti Poly Reduction Screw Ø5.50 x 25mm	A3P-5525R
Ti Poly Reduction Screw Ø5.50 x 30mm	A3P-5530R
Ti Poly Reduction Screw Ø5.50 x 35mm	A3P-5535R
Ti Poly Reduction Screw Ø5.50 x 40mm	A3P-5540R
Ti Poly Reduction Screw Ø5.50 x 45mm	A3P-5545R

Set Screw for Use with Screws and Hooks	Catalog n°
T-15 Set Screw, Regular	A3S-T15

Smooth Shank Screws

Polyaxial Smooth Shank Screws	Catalog n°
Ti Poly Smooth Shank Screw Ø3.50 x 20mm	A3P-3520-S
Ti Poly Smooth Shank Screw Ø3.50 x 22mm	A3P-3522-S
Ti Poly Smooth Shank Screw Ø3.50 x 24mm	A3P-3524-S
Ti Poly Smooth Shank Screw Ø3.50 x 26mm	A3P-3526-S
Ti Poly Smooth Shank Screw Ø3.50 x 28mm	A3P-3528-S
Ti Poly Smooth Shank Screw Ø3.50 x 30mm	A3P-3530-S
Ti Poly Smooth Shank Screw Ø3.50 x 32mm	A3P-3532-S
Ti Poly Smooth Shank Screw Ø3.50 x 34mm	A3P-3534-S
Ti Poly Smooth Shank Screw Ø4.00 x 20mm	A3P-4020-S
Ti Poly Smooth Shank Screw Ø4.00 x 22mm	A3P-4022-S
Ti Poly Smooth Shank Screw Ø4.00 x 24mm	A3P-4024-S
Ti Poly Smooth Shank Screw Ø4.00 x 26mm	A3P-4026-S
Ti Poly Smooth Shank Screw Ø4.00 x 28mm	A3P-4028-S
Ti Poly Smooth Shank Screw Ø4.00 x 30mm	A3P-4530-S
Ti Poly Smooth Shank Screw Ø4.00 x 32mm	A3P-4532-S
Ti Poly Smooth Shank Screw Ø4.00 x 34mm	A3P-4534-S

Reduction Smooth Shank Screws

Polyaxial Reduction Smooth Shank Screws	Catalog n°
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 22mm	A3P-3522R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 24mm	A3P-3524R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 26mm	A3P-3526R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 28mm	A3P-3528R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 30mm	A3P-3530R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 32mm	A3P-3532R-S
Ti Poly Reduction Smooth Shank Screw Ø3.50 x 34mm	A3P-3534R-S

Additional screw sizes available upon request.

Cross Connectors

Adjustable Rod-to-Rod Cross Connectors	Catalog n°
Ti Adjustable Rod-to-Rod Cross Connector, 31-35mm	A3X-R3135
Ti Adjustable Rod-to-Rod Cross Connector, 35-40mm	A3X-R3540
Ti Adjustable Rod-to-Rod Cross Connector, 39-49mm	A3X-R3949

Screw-to-Screw Cross Connectors	Catalog n°
Ti Screw-to-Screw Cross Connector, 33mm (30-36mm)	A3X-S33
Ti Screw-to-Screw Cross Connector, 37mm (34-40mm)	A3X-S37
Ti Screw-to-Screw Cross Connector, 41mm (38-44mm)	A3X-S41
Ti Screw-to-Screw Cross Connector, 45mm (42-48mm)	A3X-S45
Ti Screw-to-Screw Cross Connector, 49mm (46-52mm)	A3X-S49

Set Screw for Use with Adjustable Cross-Connectors	Catalog n°
T-15 Set Screw, Coned	A3S-T15C

Screw-to-Screw Cross Connector Set Screw and Nut	Catalog n°
T-15 Screw-to-Screw Cross Connector Set Screw	A3S-XT15
T-15 Screw-to-Screw Cross Connector Nut	A3S-XN

Rod Connectors

Rod-to-Rod Connectors	Catalog n°
Side-by-Side Connector, Closed, fitting Ø3.5/4.0mm	A3D-C35
Side-by-Side Connector, Closed, fitting Ø4.5/5.0mm	A3D-C45
Side-by-Side Connector, Closed, fitting Ø5.5/6.0mm	A3D-C55
Side-by-Side Connector, Open, fitting Ø3.5/4.0mm	A3D-OS35
Side-by-Side Connector, Open, fitting Ø4.5/5.0mm	A3D-OS45
Side-by-Side Connector, Open, fitting Ø5.5/6.0/6.35mm	A3D-OS55
Tandem Connector, 15mm, fitting Ø3.5/4.0mm	A3T-C35-15
Tandem Connector, 28mm, fitting Ø3.5/4.0mm	A3T-C35-28
Tandem Connector, 15mm, fitting Ø5.5/6.0mm	A3T-C55-15
Tandem Connector, 28mm, fitting Ø5.5/6.0mm	A3T-C55-28
Cable Connector	A3C

Lateral Connectors	Catalog n°
Closed Lateral Connector, 10mm	A3L-C10
Closed Lateral Connector, 15mm	A3L-C15
Open Side-Loading Lateral Connector, 10mm	A3L-OS10
Open Side-Loading Lateral Connector, 15mm	A3L-OS15
Open Side-loading Angled Lateral Connector, 15mm	A3L-OSA15
Open Side-loading Angled Lateral Connector, 25mm	A3L-OSA25

Additonal Tandem and Lateral Connectors available upon request

Set Screw for Use with Rod-to-Rod and Cable Connectors	Catalog n°
T-15 Set Screw, Flat	A3S-T15F

Titanium Rods

Titanium Straight Rods	Catalog n°
Ti Straight Rod with Axial Line Ø3.5mm x 25mm	A3R-35-025
Ti Straight Rod with Axial Line Ø3.5mm x 30mm	A3R-35-030
Ti Straight Rod with Axial Line Ø3.5mm x 35mm	A3R-35-035
Ti Straight Rod with Axial Line Ø3.5mm x 40mm	A3R-35-040
Ti Straight Rod with Axial Line Ø3.5mm x 45mm	A3R-35-045
Ti Straight Rod with Axial Line Ø3.5mm x 50mm	A3R-35-050
Ti Straight Rod with Axial Line Ø3.5mm x 60mm	A3R-35-060
Ti Straight Rod with Axial Line Ø3.5mm x 70mm	A3R-35-070
Ti Straight Rod with Axial Line Ø3.5mm x 80mm	A3R-35-080
Ti Straight Rod with Axial Line Ø3.5mm x 90mm	A3R-35-090
Ti Straight Rod with Axial Line Ø3.5mm x 100mm	A3R-35-100
Ti Straight Rod with Axial Line Ø3.5mm x 325mm	A3R-35-325
Ti Straight Rod with Axial Line Ø4.0mm x 325mm	A3R-40-325

Titanium Transition Rods	Catalog n°
Ti Transition Rod with Axial Line, Ø3.5mm to Ø5.5mm x 325mm	A3R-T35-325
Ti Transition Rod with Axial Line, Ø3.5mm to Ø5.5mm x 500mm	A3R-T35-500
Ti Transition Rod with Axial Line, Ø4.0mm to Ø5.5mm x 500mm	A3R-T45-500

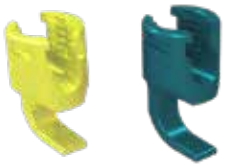
Cobalt Chrome Rods

Cobalt Chrome Straight Rods	Catalog n°
CoCr Straight Rod Ø3.5mm x 325mm	A3R-35-325K
CoCr Straight Rod Ø4.0mm x 325mm	A3R-40-325K

Cobalt Chrome Transition Rods	Catalog n°
CoCr Transition Rod Ø3.5mm to Ø5.5mm x 325mm	A3R-T35-325K

Additional rod sizes available upon request.

Laminar Hooks



Laminar Hooks	Catalog n°
Laminar Hook, 4.5mm	A3H-L45
Laminar Hook, 6.5mm	A3H-L65

Additonal hooks and sizes available upon request

Revision Rods

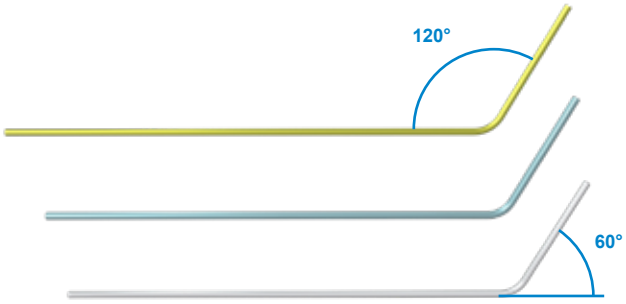
Z-Rods	Catalog n°
Ti Z-rod Ø3.5mm, 7mm Offset, 325mm	A3ZR-357-325
Ti Z-rod Ø3.5mm, 9mm Offset, 325mm	A3ZR-359-325
Ti Z-rod Ø4.0mm, 7mm Offset, 325mm	A3ZR-407-325
Ti Z-rod Ø4.0mm, 9mm Offset, 325mm	A3ZR-409-325
CoCr Z-rod Ø3.5mm, 7mm Offset, 325mm	A3ZR-357-325K
CoCr Z-rod Ø3.5mm, 9mm Offset, 325mm	A3ZR-359-325K

Additonal rod sizes available upon request.

Occipital Implants

Occipital Plates	Catalog n°
Adjustable Occipital Plate, 32mm	A3OP-A32
Adjustable Occipital Plate, 36mm	A3OP-A36
Adjustable Occipital Plate, 42mm	A3OP-A42
Adjustable Occipital Plate, 48mm	A3OP-A48

Occipital Screws	Catalog n°
Ø4.5mm Occipital Bone Screw, 6mm	A3OS-4506
Ø4.5mm Occipital Bone Screw, 8mm	A3OS-4508
Ø4.5mm Occipital Bone Screw, 10mm	A3OS-4510
Ø4.5mm Occipital Bone Screw, 12mm	A3OS-4512
Ø4.5mm Occipital Bone Screw, 14mm	A3OS-4514
Ø4.5mm Occipital Bone Screw, 16mm	A3OS-4516
Ø5.0mm Occipital Bone Screw, 6mm	A3OS-5006
Ø5.0mm Occipital Bone Screw, 8mm	A3OS-5008
Ø5.0mm Occipital Bone Screw, 10mm	A3OS-5010
Ø5.0mm Occipital Bone Screw, 12mm	A3OS-5012
Ø5.0mm Occipital Bone Screw, 14mm	A3OS-5014
Ø5.0mm Occipital Bone Screw, 16mm	A3OS-5016



Occipital Rods	Catalog n°
Ø3.5mm Ti Occipital Rod, 325mm x 60° (120°)	A3OR-35-6032
Ø4.0mm Ti Occipital Rod, 325mm x 60° (120°)	A3OR-40-6032
Ø3.5mm CoCr Occipital Rod, 325mm x 60° (120°)	A3OR-35-6032K

04. Instrument Ordering Information

	ASTRA-OCT Instruments	Catalog n°
Implant Prep Instruments	Awl	6600-45
	Upper Thoracic Pedical Probe	6600-48
	Cervical Probe, Straight	6600-49-S
	Fixed Drill Guide, 10mm (optional)	6600-60-10
	Fixed Drill Guide, 12mm	6600-60-12
	Fixed Drill Guide, 14mm (optional)	6600-60-14
	Fixed Drill Guide, 16mm (optional)	6600-60-16
	Adjustable Drill Guide	6600-60-A
	Adjustable Drill Guide Sleeve, 8-30mm	6600-61-A
	Drill Bit, Ø2.4mm	6600-70-24
	Polyaxial Screw Taps Ø3.0mm	6600-71-30
	Polyaxial Screw Taps Ø3.5mm	6600-71-35
	Polyaxial Screw Taps Ø4.0mm	6600-71-40
	Polyaxial Screw Taps Ø4.5mm	6600-71-45
	Polyaxial Screw Taps Ø5.0mm	6600-71-50
	Polyaxial Screw Taps Ø5.5mm (optional)	6600-71-55
	Sounding Probes, Single End	6600-43-S
	Sounding Probes, Double End	6600-43-D
Drivers/ Holders	Polyaxial Screwdriver	6600-89-PS
	Polyaxial Screwdriver, Dedicated Reduction (optional)	6600-89-DR
	Self-Retaining T15 Driver	6600-T15-3B
	Head Adjuster	6600-75
	Tulip Holder Forceps (optional)	6600-08
	Connector Holder Forceps	6600-10
	Rod Holder Forceps	6600-11
	Rod Clamp	6600-12
Implant Manipulation	Rod Bender	6600-16
	Rod Cutter	6600-95
	Multi-purpose Cutter (optional)	6600-95-M
	Sagittal Bender, Right	6600-94-R
	Saggital Bender, Left	6600-94-L
	Rod Persuader	6600-01
	No Handle Rocker	6600-05-NH
	Rod Pusher (optional)	6600-34
	Distractor	6600-41
	Compressor	6600-42

	ASTRA-OCT Instruments	Catalog n°
Final Tighten	Torque Limiting Handle, Straight	6600-02-S
	Anti-Torque	6600-98
	Cross Connector Anti-Torque	6600-99
	Cross Connector Nut Driver	6600-19
	T15 Driver	6600-T15
Other	Racheting Palm Handle (optional)	6600-03-P
	Racheting Straight Handle	6600-03-SB
	Rod Template, 180mm	6600-35-R180
	Rod Template, 240mm (optional)	6600-35-R240
	X-C Size Selection Card	6600-47
	Screw Selection Device	6600-93
Cases	Standard Instrument Case	6600-100
	Standard Implant Case	6600-310
	Regular Screw Caddy	6600-310-1
	Smooth Shank Screw Caddy	6600-310-2
	Rod & Cross Connector Caddy	6600-310-3
	Miscellaneous Connectors Caddy	6600-310-4
	Occipital Fixation Case	6601-730
	Occipital Implants Caddy	6601-730-1
Occipital Instruments	Large Ratcheting Handle	6600-03-S
	Occipital Plate Bending Holder	6601-16-H
	Occipital Plate Tip Bender	6601-16-T
	Occipital Plate Drill Guide, 6mm & 8mm	6601-60-1B
	Occipital Plate Drill Guide, 10mm & 12mm	6601-60-2B
	Occipital Plate Drill Guide, 14mm & 16mm	6601-60-3B
	Occipital Plate Tap/Driver Guide	6601-60-D
	Ø3.2mm Occipital Drill Bit	6601-70-32
	Ø3.2 Flexible Occipital Dril Bit	6601-70-32-F
	Ø4.5mm Occipital Screw Tap	6601-71-45
	Ø4.5 Flexible Occipital Screw Tap	6601-71-45-F
	Ø5.0mm Occipital Screw Tap	6601-71-50
	Ø5.0 Flexible Occipital Screw Tap	6601-71-50-F
	Flexible T15 Self-Retaining Driver	6601-T15-3F
	Flexible T15 Driver	6601-T15-F

05. Surgical Technique: Cervicothoracic Procedure

Patient Positioning

1

Position the patient supine with head in neck in proper alignment on a radiolucent table that is compatible with a fluoroscopic C-Arm.

All the hardware used to position the patient should also be radiolucent.

Preparing a Pilot Hole with the Awl

2

Use the Awl (6600-45) to break the cortical surface. The Awl has a shoulder that limits penetration to 7mm.

Drilling a Hole with the Fixed or Adjustable Drill Guide

3

Use the Ø2.4mm Drill (6600-70-24) with the Fixed Drill Guide (6600-60-12) to drill to the depth specified on the guide. A 12mm Fixed Drill Guide is provided standard in the set. A 10mm, 14mm, or 16mm Fixed Drill Guide can be provided upon request.

Alternatively, the Adjustable Drill Guide (6600-60-A) and Adjustable Drill Guide Sleeve (6600-61-A) can be used to drill to depths ranging from 8mm to 30mm. Press the button on the Adjustable Drill Guide and insert the Adjustable Drill Guide Sleeve by setting the yellow line to the desired depth.

Note: inspect and clean drill guide cannula after each surgery.

Cervical and Thoracic Probe

4

There are two penetrating probes in the set:

The Straight Cervical Probe (6600-49-S) creates a smaller pathway, suitable for Ø3.5mm and Ø4.0mm screws. Marking depths from tip of cervical probe back are 6,10, 14, 20, 30, 40mm respectively.

The Upper Thoracic Pedicle Probe (6600-48) creates a larger pathway, suitable for Ø4.5mmm, Ø5.0mm and Ø5.5mm screws. Marking depths from the tip of the Thoracic Probe back are 10, 20, 30, 40, and 50mm respectively.

Note: DO NOT use Thoracic Probe for Ø3.5 and 4.0mm screws.

Checking Hole Integrity with Sounding Probe

5

There are several sounding probe options in the standard set, including different stiffness and curvature. The sounding probes can be used to confirm the integrity of the hole and the assess depth.

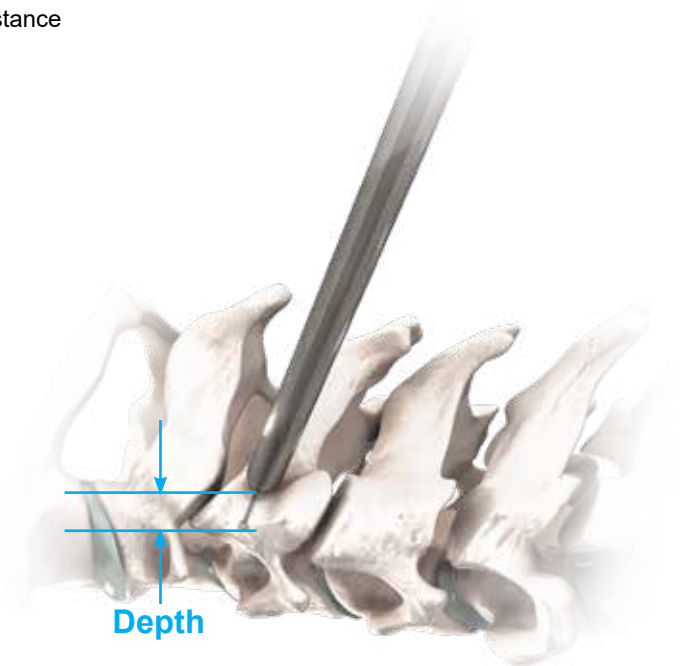
For the Double End Sounding Probe (6600-43-D) marking depths from the tip of the probe back are 10, 15, 20, 25, 30, and 35mm respectively.

For the Single End Sounding Probe (6600-43-S), marking depths from the tip of the probe back are 30, 40, 50, 60, and 70mm respectively.

Confirming Hole Depth With Screw Selection Device

6

The Screw Selection Device (6600-93) can be used to select the appropriate length screw. The reading on the scale represents distance from the shoulder of the sleeve to the end of the ball tip (as shown).



Tapping

7

The polyaxial screws are self-tapping. However, it is recommended to prepare the hole by tapping, especially in the case of dense bone. Taps (6600-71-XX) are available in diameters 3.0 to 5.5mm in 5mm increments. The taps are only slightly undersized from the labeled screw size. Therefore, it is customary to initially tap one size below the intended screw size.

Note: The threaded length of each tap is 15mm. Additional depth markingkings are present at 20mm, 25mm, and 30mm.

Screw Placement (Polyaxial Screws)

8

» Polyaxial Screws are inserted using a Polyaxial Screwdriver (6600-89-PS)
» The Polyaxial Screwdriver is used in conjunction with the Ratcheting Handle (6600-03-SB)

For insertion of Reduction Screws use the Dedicated Reduction Polyaxial Screwdriver.

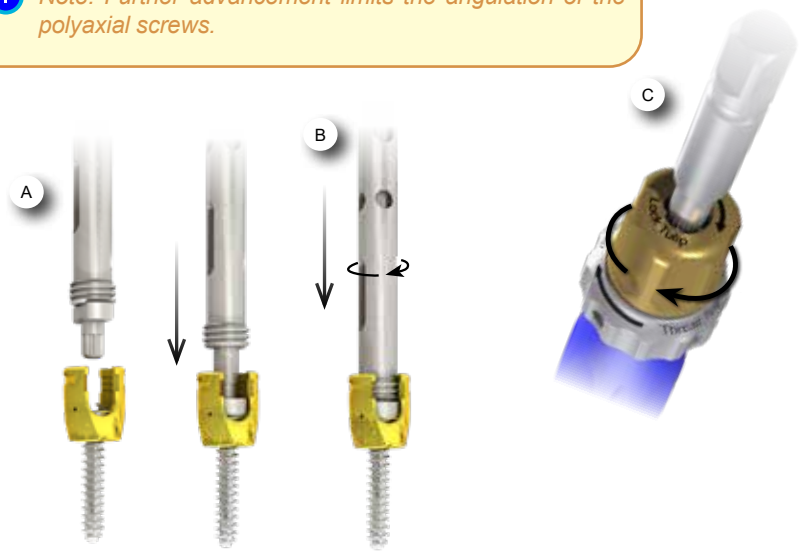
To load a Polyaxial Screw, insert the boss of the Screwdriver into the U-shaped slot of the screw tulip (A). Simultaneously rotate the screw shank to position the driver tip into the shank's hexalobe socket. Slide down and turn the driver sleeve clockwise to engage the tulip thread, then tighten (B). Tighten the locking knob onto the sleeve to prevent inadvertent release of the screw (C). Once fully engaged, the screw can be inserted into the vertebral body.

Implant the Polyaxial Screw into the desired lateral mass or pedicle, and advance to a depth where full angulation of the polyaxial head is maintained.

Repeat the process until all polyaxial screws are placed.

It is advised to align screwdriver with shank in order to pull out smoothly.

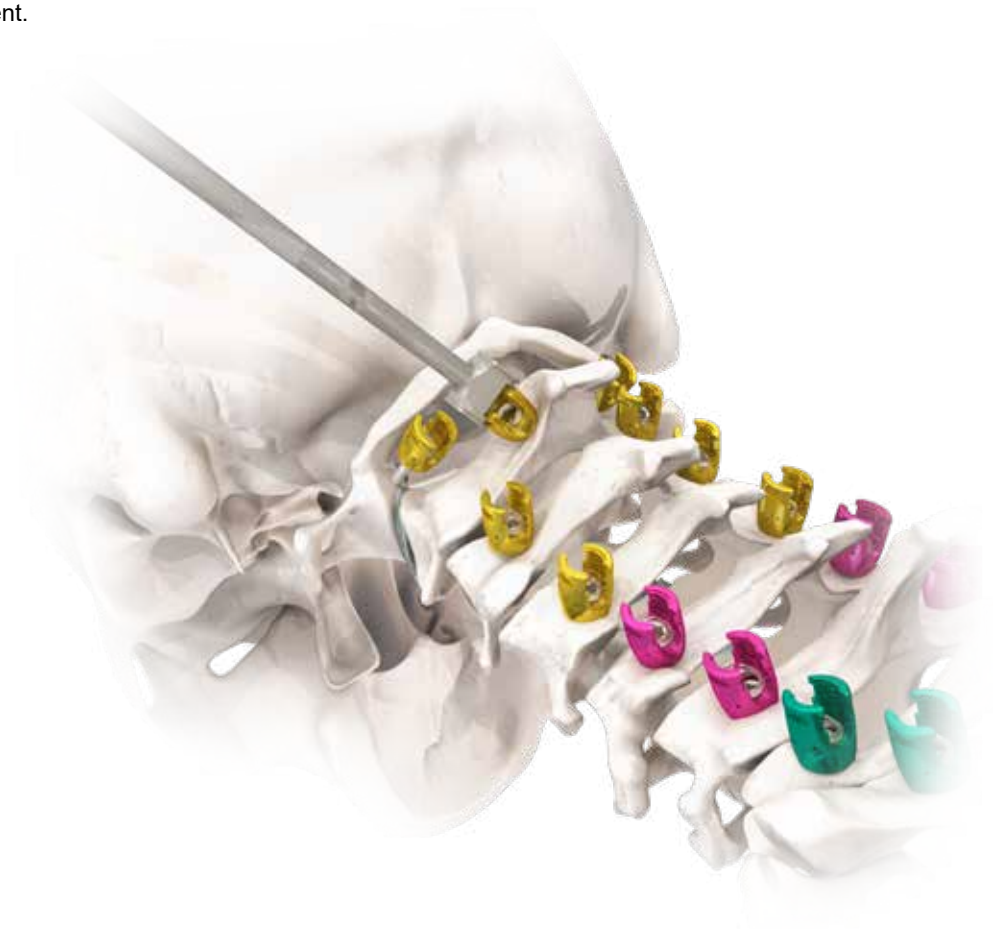
Note: Further advancement limits the angulation of the polyaxial screws.



Adjusting Heads of Polyaxial Screws

9

The Head Adjuster (6600-75) can be used to align the heads of the polyaxial screws in preparation for rod placement.



Rod Cutting

10

The Rod Cutter (6600-95) has two holes, one designated for Ø3.5mm rods and one for Ø4.0mm rods. The rod will be cut 6mm from the entry of the hole, since the cutting occurs at the center of the two sliding cutting plates, which are 6mm thick each. The rod should be cut to the proper size before implantation.

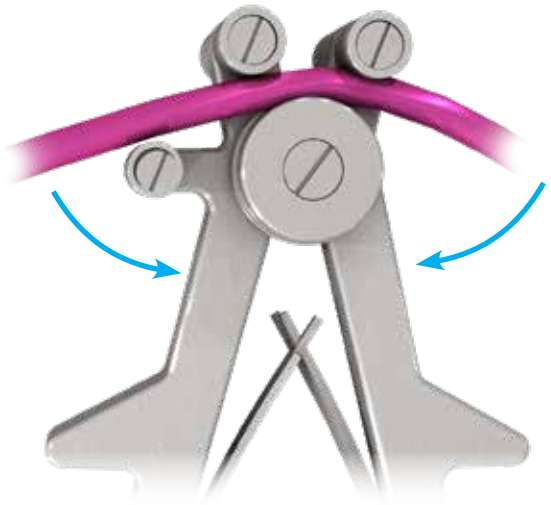
The Rod Cutter also has a u-slot designated for Ø3.5mm Titanium Rod. Note, the u-slot should only be used for Titanium Rods and is marked as such. The u-slot is not intended to cut Cobalt Chrome rods and will result in damage to the instrument.

Rod Bending

11

The malleable Rod Template (6600-35-RXXX) can be used to determine to required contour of the rod to fit the implants.

Use the Rod Bender (6600-16) to contour the rod as required. The large roller on the Rod Bender has two different diameters, which provide two different spacing options during rod bending.

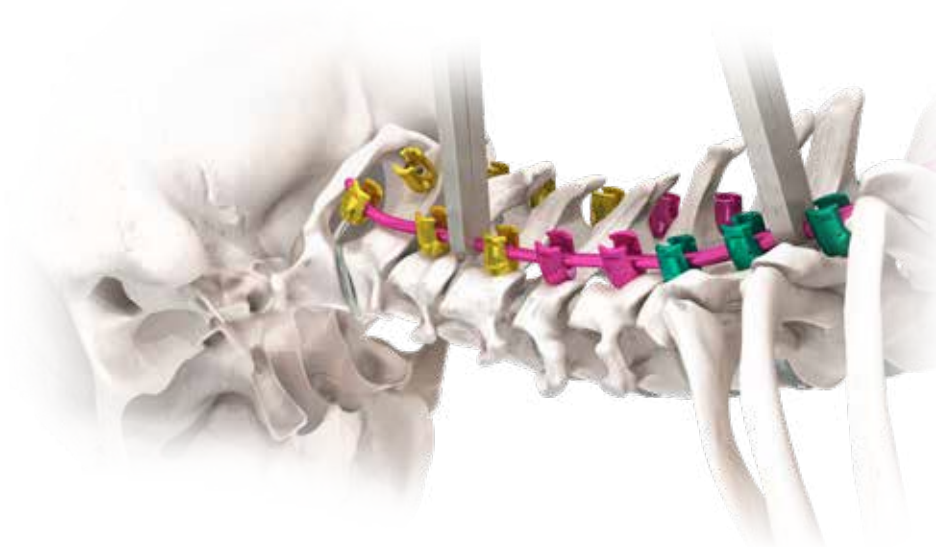


Note: This side for Occipital Plate bending only.

Rod Placement

12

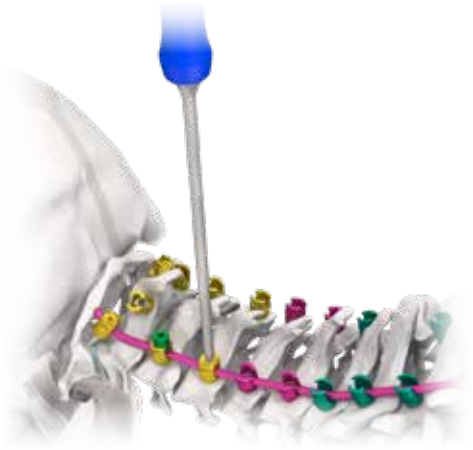
Use the Rod Holder Forceps (6600-11) or the Rod Clamp (6600-12) to place the rod.



Set Screw Placement

13

Use the Self-Retaining T15 Driver (6600-T15-3B) to pick up the set screw from the implant caddy. Then thread the set screw into its associated implants.



The Self-Retaining T15 Driver is intended for provisional tightening only.

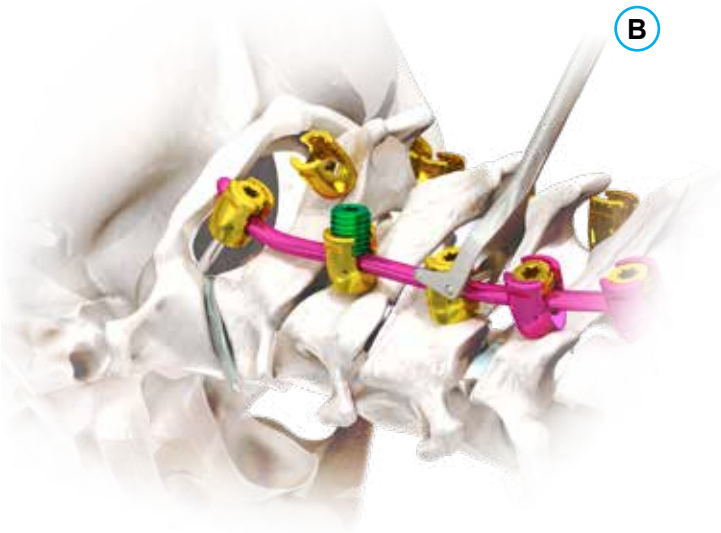
Rod Reduction

14

A To reduce the rod, slide the tips of the Persuader (6600-01) over the implant. The Persuader tips will snap on and lightly grasp the implant. Then squeeze the Persuader arms to lock onto the implant and reduce the rod. Once the the rod is reduced, use the Self-Retaining T15 Driver (6600-T15-3B) to introduce the set screws through the Persuader and capture the rod. In order to disengage the Persuader tips, release the arms, rotate the instrument 90°, and pull up.

B Alternatively, the Rocker (6600-05-NH) can be used to reduce the rod. Slide the tips of the Rocker into the slot of the implant. Ensure that the Rocker tips are centered on the implant and engaged in the implant recesses. Rock the instrument to reduce the rod. Once the the rod is reduced, use the Self-Retaining T15 Driver to introduce the set screw and capture the rod.

Other available reduction options include Reduction Screws (**C**) or and optional Rod Pusher (6600-34).

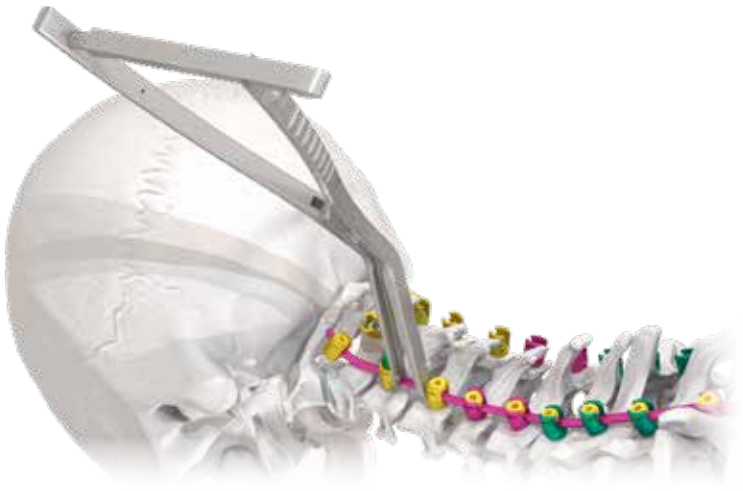


Care should be taken with any of the reduction methods. Improper instrument use may loosen implants or damage the residual facets and other bony anatomy.

Compression & Distraction

15

Once the rod is secured in the implants, use Compressor (6600-42) or Distractor (6600-41) as required. The T15 Driver (6600-T15) attached to a handle can be used to loosen and/or tighten the set screws.



Final Tightening

16

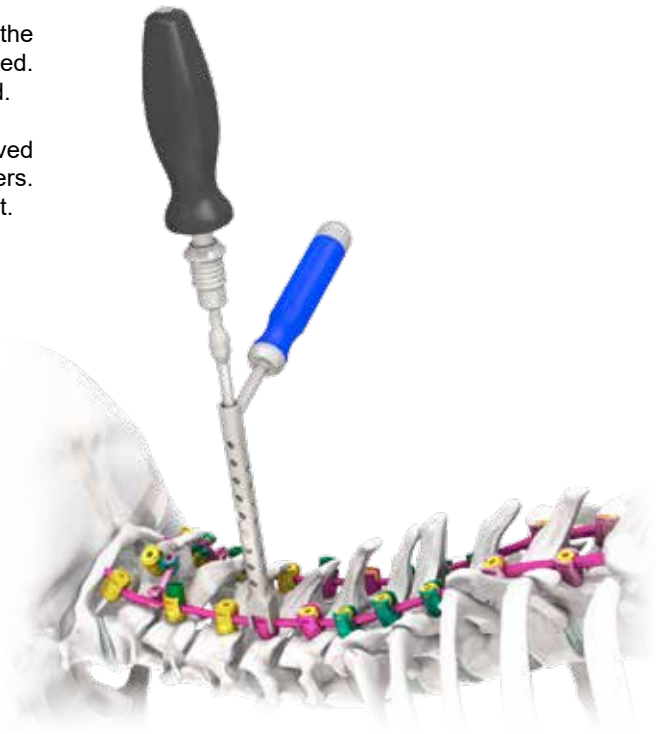
Use the T15 Driver (6600-T15) attached to the black Torque-Limiting Handle (6600-02-S) to perform final tightening to 3 N·m.

For most implants, the Anti-Torque (6600-98) can be used to stabilize the rod during final tightening.

If space does not allow direct placement of the Anti-Torque over the implant, place it at the nearest position to the implant being final tightened. Alternatively, the Rod Clamp (6600-12) can be used to stabilize the rod.

After final tightening of reduction screws, reduction tabs may be removed with a gentle rocking motion using standard operating room needle holders. Alternatively, Generic Forceps (4000-10) can be provided upon request.

Note: The Torque-Limiting Handle is the only black handle in the set.



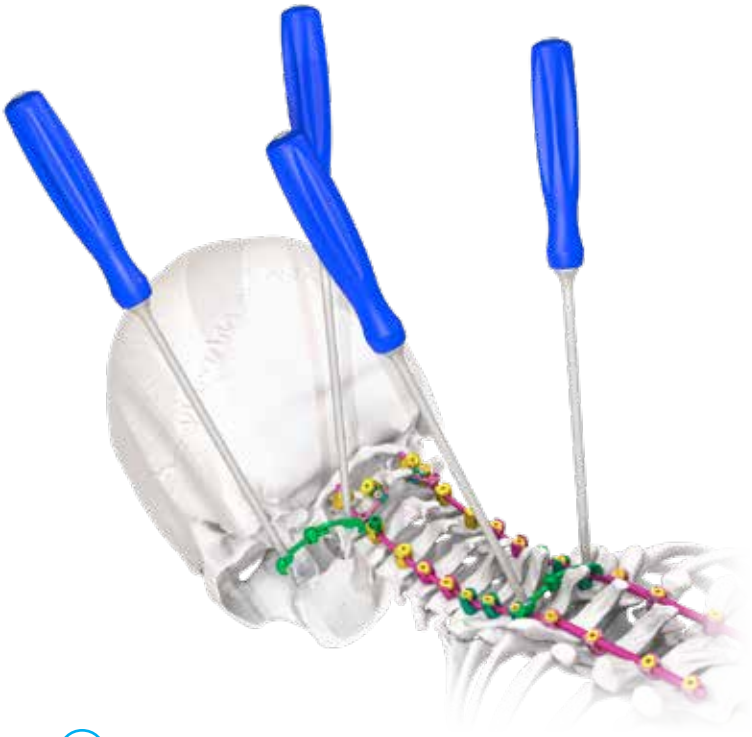
Rod-to-Rod Cross Connector Placement

16

Use the Cross Connector Selection Card (6600-47) to assist in identifying the proper fitting Cross Connector.

Place the cross connector onto the rod and use the Self-retaining T15 Driver (6600-T15-3B) to finger tighten the outside set screws first.

Second, use the Self-retaining T15 Driver to finger tighten the central screw to fixate the Cross Connector.



Rod-to-Rod Cross Connector Final Tightening

17

First, use the T15 Driver (6600-T15) attached to the Torque-Limiting Handle (6600-02-S) to final tighten the outside set screws. The standard Anti-torque (6600-98) or Rod Clamp (6600-12) can be placed nearby to stabilize the rod during final tightening.

Second use the T15 Driver attached to the Torque-Limiting Handle, along with the Cross Connector Anti-torque (6600-99), to final tighten the central screw.

Note: The Torque-Limiting Handle is the only black handle in the set.

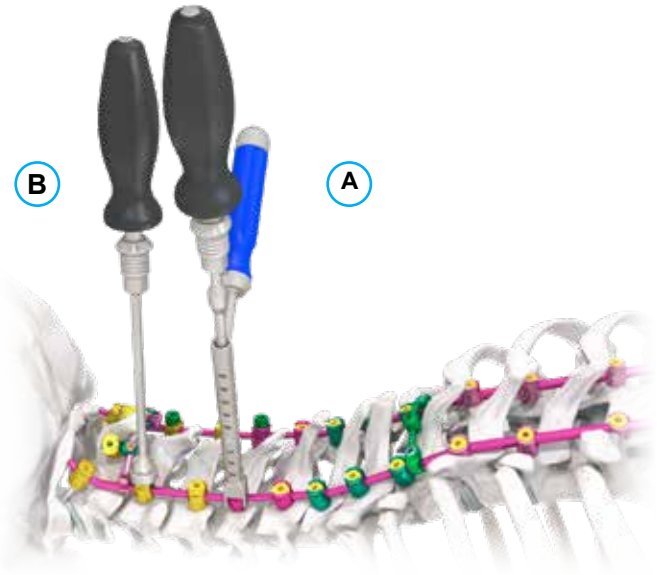
Screw-to-Screw Cross Connectors

A When using the Screw-to-Screw Cross Connector, use the tall green set screw (A3S-XT15) in the implants at the selected level. Final tighten the set screws using the T15 Driver (6600-T15), Torque-Limiting Handle (6600-02-S), and Anti-torque (6600-98).

Note: The set screw must be final tightened prior to placement of the Screw-to-Screw Cross Connector. Failing to final tighten the set screw first can result in implant loosening.

Use the Cross Connector Selection Card to assist in identifying the proper fitting Screw-to-Screw Cross Connector. Each Screw-to-Screw Cross Connector has a range of ±3mm. Place the Screw-to-Screw Cross Connector over the tall green set screws. The Rod Bender can be used to slightly adjust the contour of the Screw-to-Screw Cross Connector, in order to seat it flush with the tops of the implants.

B Attach the Cross Connector Nut Driver (6600-19) to the Torque-Limiting Handle. Use the Cross Connector Nut Driver to pick up the Cross Connector Nut from the implant caddy. Thread the Cross Connector Nut onto the tall green set screws and final tighten to secure the Screw-to-Screw Cross Connector. The Anti-torque or Rod Clamp can be placed nearby to stabilize the rod.



Note: The Torque-Limiting Handle is the only black handle in the set.

Note: If a Screw-to-Screw Cross Connector is desired at the level of a reduction screw, the reduction tabs will need to be removed first. In order to remove the reduction tab, tighten a regular set screw (A3S-T15) into the reduction screw. Next, removed the reduction tabs with a gentle rocking motion using standard room needle holders. Discard the regular set screw and then proceed to follow the instructions above.

06. Surgical Technique: Cervico-occipital Procedure

Occipital Plate Bending

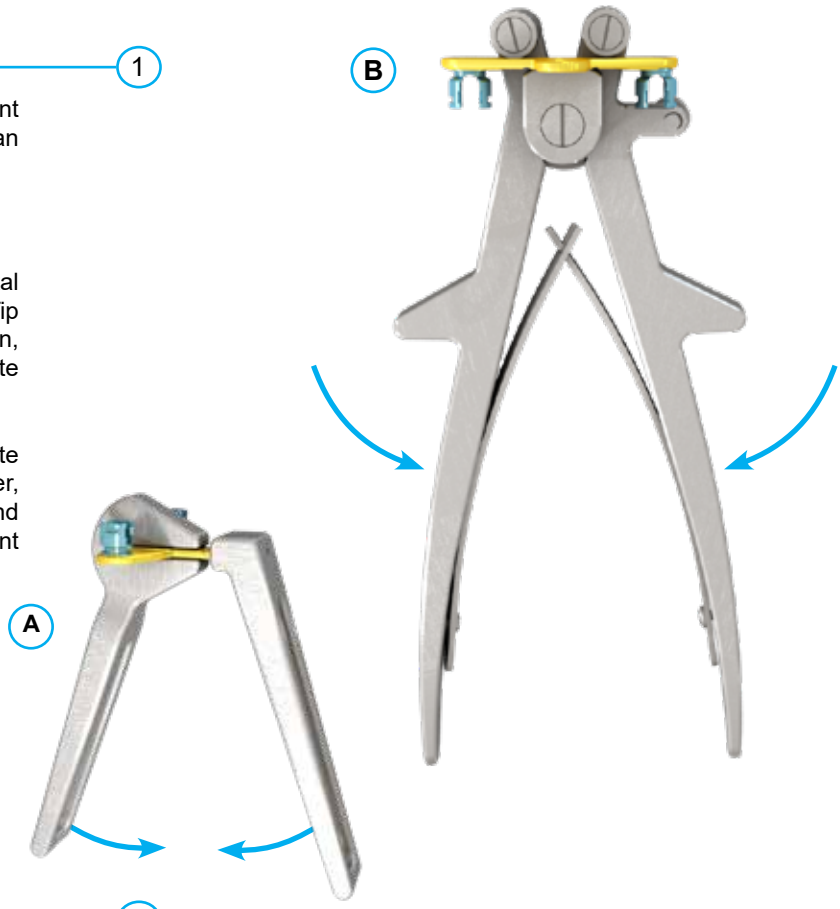
1

Select the appropriate Occipital Plate size to match patient anatomy. Together, the two tulips in the Occipital Plate can translate to accomodate ±4mm.

Bend Ocipital Plate to match patient anatomy.

A To bend the top tip of the Occipital Plate, use the Occipital Plate Bending Holder (6601-16-H) and the Occipital Plate Tip Bender (6601-16-T). Fully insert the Occipital Plate, as shown, and squeeze the bender arms together. to bend in the opposite direction, flip the Occipital Plate.

B To bend the wings of the Occipital Plate, use the Rod & Plate Bender (6600-16). Center the Occipital Plate on the flat roller, as shown, with the tulip side down. Take care not to over-bend the Occipital Plate, as the Occipital Plate wings cannot be bent in reverse.



Occipital Plate Placement

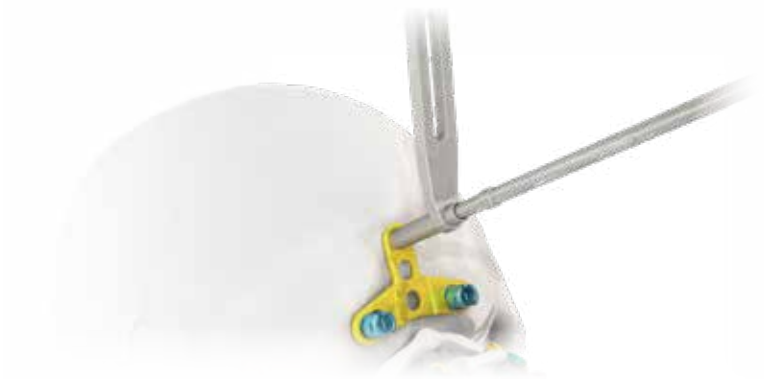
2

Use Occipital Plate to mark location of first hole.

Drill first hole using Ø3.2mm Drill Bit (6601-70-32) and the Occipital Drill Guide (6601-60-1), The use of power is recommended for efficient penetration. Increase drilling depth in increments, up to the desired depth, using a sounding probe to conform the integrity of the hole after each increment. Drill Guides are available in 2mm increments from 6mm to 16mm.

Remaining holes may be drilled after placement of the first Occipital Screw.

Tip: When using the Flexible Drill Bit, drill penetration can be improved by initially breaking the hard cortical surface with a burr.



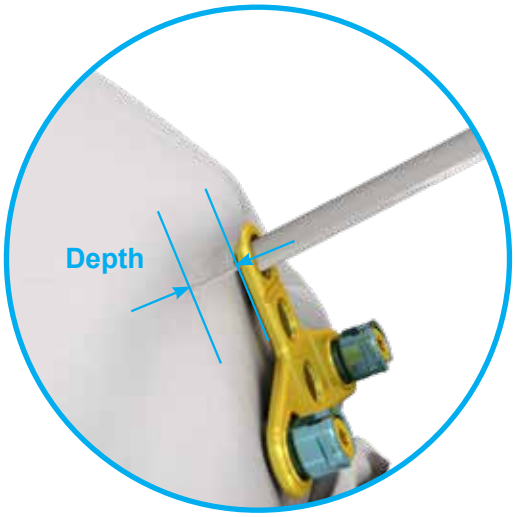
Optional Flexible Drill Bit (6601-70-32-F)

Check First Hole Depth

3

Use the Screw Selection Device (6600-93) to select the proper length Occipital Screw.

The Screw Selection Device assesses hole depth from the surface of the bone (bottom of the Occipital Plate), which corresponds to the labeled Occipital Screw lengths. A longer screw length may be selected, when deemed appropriate, if a particular Occipital Plate hole is raised off the surface of the bone, due to patient anatomy.



Tap Hole

4

The occipital bone must be tapped, as Occipital Screws are not self-tapping. Use Ø4.5mm Occipital Screw Tap (6601-71-45) with the lagoon-colored ring to tap hole; establish tapping depth by monitoring depth markings on tap or by using alongside with the Occipital Drill Guide (6601-60-X).

The threaded length of the tap is 7mm. Depth markings on the Tap are as follows:

- Solid line at 8, 12, 16mm
- Dotted line at 10, 14, 18mm

Note, when using the Drill Guide to control tapping depth, take care not to strip the bone once the tap reaches the Drill Guide stop.

Note, the Ø5.0mm Occipital Screw Tap (6601-71-50) with a pink-colored ring should only be used, if required, when implanting a rescue Ø5.0mm Occipital Screw.

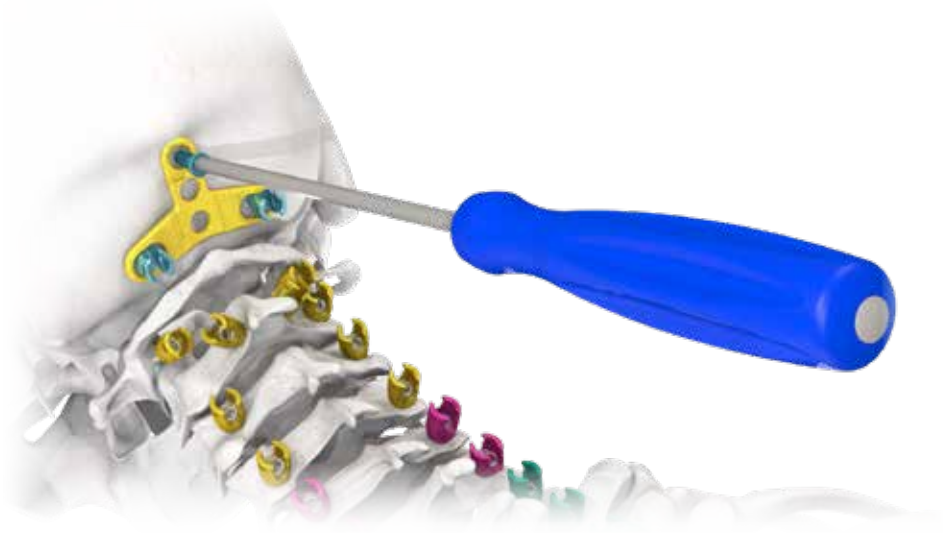
Optional Flexible Tap (6601-71-45-F) with Occipital Drill Guide (6601-60-X)

Implant Occipital Screw

5

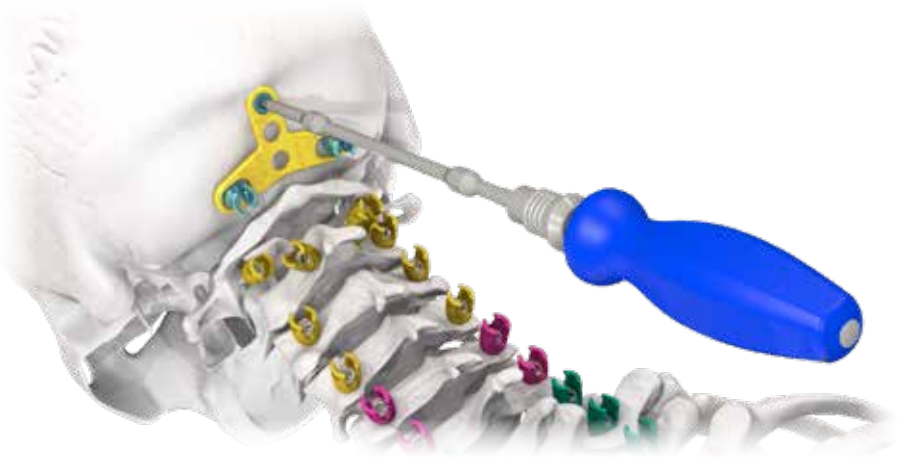
Using the Self-retaining T-15 Driver (6600-T15-3B), stab-and-grab the Occipital Screw from the caddy and begin implantation.

To use the Flexible T15 Self-retaining Driver (6601-T15-3F), preload the driver through the guide barrel, then stab-and-grab the Occipital Screw from the caddy.



Optional Flexible T15 Self-retaining Driver (6601-T15-3F) with Occipital Plate Tap/ Driver guide (6601-60-D)

Use the T15 Driver (6600-T15) and Large Ratcheting Handle (6600-03-S), especially in the case of hard bone, for final screw positioning and tightening. Upon proper Occipital Screw tightening, the Occipital Screw will be in contact with the Occipital Plate, and the Occipital Plate will be completely immobilized.



Bend Rod

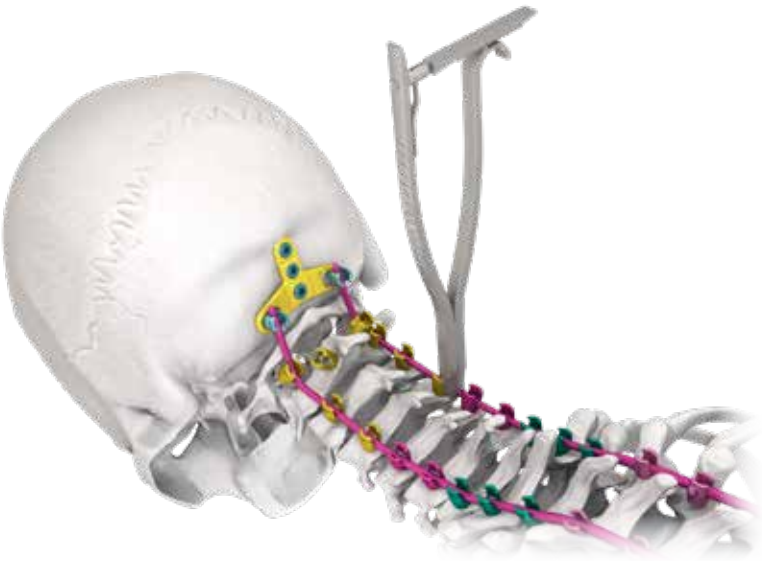
6

Use Rod & Plate Bender (6600-16) to bend rod to match patient anatomy.

Rod Placement

7

Use the Rod Holder Forceps (6600-11) or the Rod Clamp (6600-12) to place the rod.

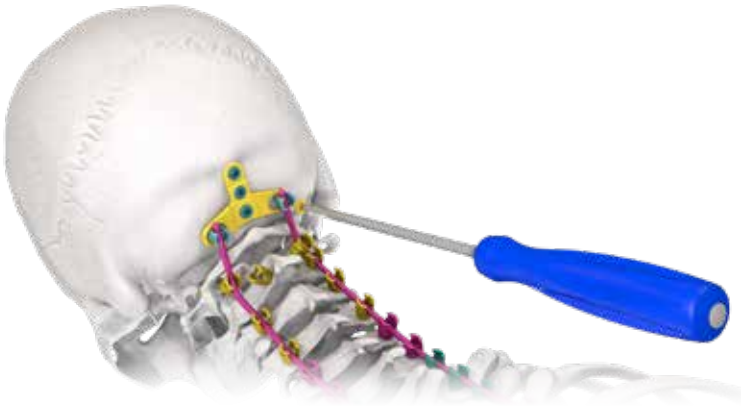


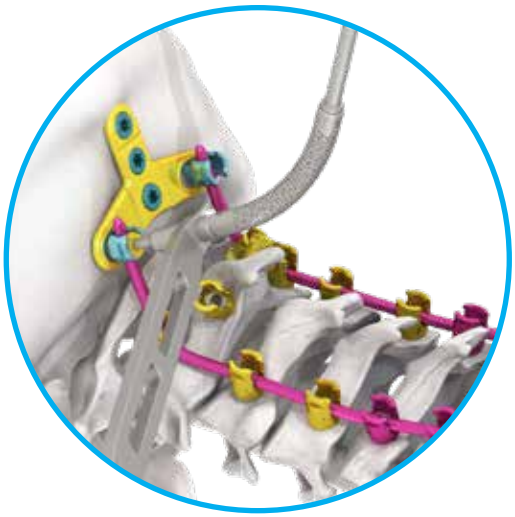
Place Set Screws

8

Using the Self-retaining T15 Driver (6600-T15-3B), stab-and-grab the set screw from the caddy and provisionally tighten into the tulip.

To use the Flexible T15 Self-retaining Driver (6601-T15-3F), preload the driver through the guide barrel, then stab-and-grab the Set Screw from the Caddy.



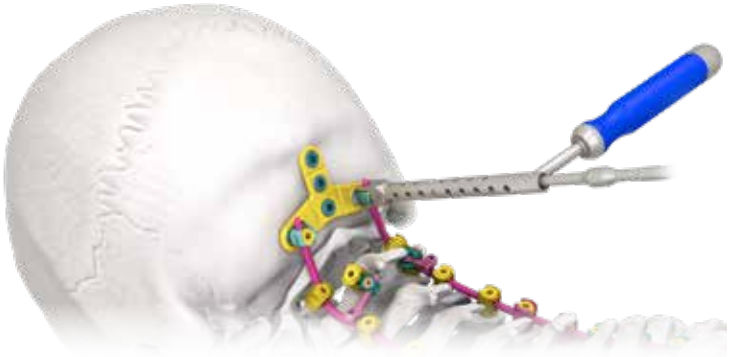


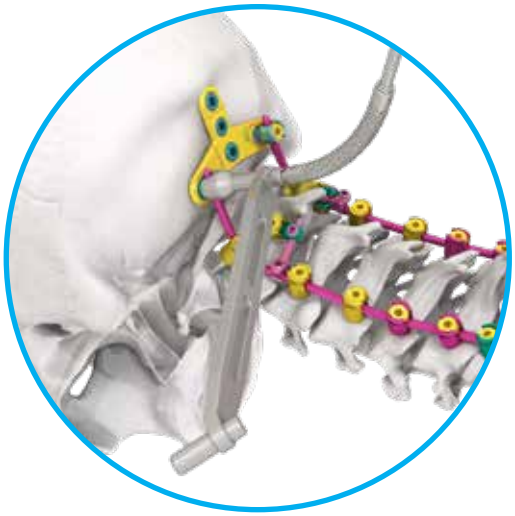
Optional Flexible T15 Self-retaining Driver (6601-T15-3F) with Occipital Plate Tap/ Driver guide (6601-60-D)

Final Tightening

9

Use the Torque Limiting Handle (6600-02-S), T15 Driver (6600-T15), and the Anti-torque (6600-98) to perform final tightening of set screws to 3N·m.





Optional Flexible T15 Self-retaining Driver (6601-T15-3F) with Occipital Plate Tap/ Driver guide (6601-60-D)

07. Instructions for Use

ASTRA-OCT SPINE SYSTEM

CAUTION: USA law restricts this device to sale by or on the order of physician.

1. DESCRIPTION AND IMPLANTS MATERIAL

The ASTRA-OCT Spine System consists of a series of polyaxial screws, occipital screws, occipital plates, hooks, rods, lateral connectors, rod-to-rod connectors, set screws, and cross connectors.

The ASTRA-OCT Spine System components are available in titanium alloy conforming to ASTM F136 specifications. Rods are also available in Cobalt Chromium alloy conforming to ASTM F1537 specifications.

2. INDICATIONS FOR USE

The ASTRA-OCT Spine System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3):

- Traumatic spinal fractures and/or Traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g. pseudoarthrosis);
- Tumors involving the cervical/thoracic spine; and
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The ASTRA-OCT Spine System implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the ASTRA-OCT Spine System rods may be connected to other occipital cervical thoracic or thoracolumbar stabilization rod systems ranging in diameter from 3.5mm to 6.35mm, including the ASTRA or APEX Spine Systems, using corresponding connectors.

3. PATIENT SELECTION.

In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

- **The patient's weight.** An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

- **The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

- **A condition of senility,** mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

- **Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
- **Smoking.** Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

4. PACKAGING.

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to SpineCraft.

5. CLEANING AND DECONTAMINATION.

Unless just removed from an unopened SpineCraft package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineCraft. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Unless marked sterile and clearly labelled as such in an unopened sterile package provided by the company.

6. STERILIZATION.

Implants and instruments of the ASTRA-OCT Spine System are supplied clean and not sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ASTRA-OCT instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the steam pre-vacuum process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Blue Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Rigid Sterilization Container: The following Aesculap sterilization rigid container components are validated for use:

- Aesculap Extra-Long Container, Perforated Bottom, 5½ -inch (P/N JN443)
- Aesculap Extra-Long Container, Perforated Bottom, 8-inch (P/N JN445)
- Aesculap Extra-Long Container, Lid with Retention Plates (P/N JK490)
- Aesculap Single use 7 ½" diameter filter with indicator dot (P/N US751)
- Aesculap Single use 7 ½" diameter filter (P/N US994)

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

7. CONTRAINDICATIONS.

Contraindications include but are not limited to:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
- Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
- Patients with inadequate bone stock or quality. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.
- Any condition not described in the Indications for Use.
- Signs of local inflammation
- Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
- Use with components of other systems.
- Reuse or multiple uses.
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication.
- Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition,
- The patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.
- See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION

DEVICES section of this insert.

A. IMPORTANT NOTE TO OPERATING SURGEON

ASTRA-OCT Spine System implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used or if a pseudo-arthrosis develops.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

B. WARNINGS

- **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

- **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION**. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

- **MIXING METALS CAN CAUSE CORROSION**. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

C. PRECAUTIONS

- **SURGICAL IMPLANTS MUST NEVER BE REUSED**. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

- **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

- **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

- **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

- **CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

- **IMPLANTS FATIGUE.** Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

- **PREVIOUS SPINAL SURGERY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

- **COMPATIBILITY:** Components from two different systems should not be mixed.

- **MAGNETIC RESONANCE (MR) SAFETY:** The ASTRA-OCT Spine System has not been evaluated for safety and compatibility in the MR environment. The ASTRA-OCT Spine System has not been tested for heating or migration in the MR environment.

D. PRECAUTIONS RELATED TO USAGE OF PEDICLE SCREW

- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.
- Refer to the individual system surgical technique manuals for additional important information.
- SpineCraft Spinal Systems components should not be used with components from other manufacturers.
- During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.
- After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.
- These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.
- The implanting surgeon should consider carefully the size and type of implants most suitable for the patient's age, size and weight.

E. POSSIBLE ADVERSE EFFECTS

- Bending or fracture of implant.

- Loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Infection, early or late.
- Nonunion, delayed union.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
- Bursitis.
- Paralysis.
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Death.
- Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
- Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
- Damage to lymphatic vessels and/or lymphatic fluid exudation.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

F. PREOPERATIVE PLANNING AND POSTOPERATIVE CARE

- Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components.
- Accepted surgical practices should be followed for postoperative care.
- Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.
- Excessive physical activity and trauma affecting the implanted devices have been implicated in premature failure by fracture, migration and/or wear of the implants.
- Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. The patient should be cautioned to govern his/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient
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- PRODUCT COMPLAINTS

10. PRODUCT COMPLAINTS.

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, SpineCraft or our Authorized European Representative. Further, if any of the implanted ASTRA-OCT Spine System component(s) ever “malfunctions”, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any SpineCraft product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s) or product UDI, your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

LIMITED WARRANTY AND DISCLAIMER: ASTRA-OCT SPINE SYSTEM PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at +1 630-920-7300.

SURGICAL TECHNIQUE MANUAL COULD BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

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